An inflatable nasal packing device (10) employing a flexible keel (12) that can be removably inserted through the nasal cavity (50) and into the nasopharynx (60). A first inflatable bag (30) is attached to the anterior portion of the keel (12) that remains within the nasal cavity (50), and a second inflatable bag (40) is attached to the posterior portion of the keel (12) extending into the nasopharynx (60). The bags (30, 40) completely surround the keel (12) and are much larger than the relevant portions of the nasal cavity (50) and nasopharynx (60). This helps to ensure that the bags (30, 40) conform to irregularities in and apply uniform pressure to the interior surfaces of the nasal cavity (50), including the nasal septum (70). The device is initially inserted into the nasal cavity (50) with the bags (30, 40) in a deflated condition, and either or both of the bags (30, 40) are then inflated with air or fluid. When inflated, the first bag (30) conforms to and blocks the anterior portion of the nasal cavity (50) without substantial distension. Similarly, the second bag (40) conforms to and blocks the nasopharynx (60) without substantial distention. Inflation and deflation of the bags (30, 40) is controlled by two catheters (32, 42) extending along the keel (12).
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INFLATABLE NASAL PACKING DEVICE

BACKGROUND OF THE INVENTION

1. **Field of the Invention.** The present invention relates generally to the field of nasal packing devices. More specifically, the present invention discloses an inflatable nasal packing device that can be used to treat both anterior and posterior nose bleeds.

2. **Statement of the Problem.** Physicians are frequently called upon to treat nasal bleeding (epistaxis) caused by tissue dessication, trauma, or disease, or resulting from surgery. A patient can quickly lose a large quantity of blood through nasal bleeding due to the extensive blood supply to the nose and nasopharynx. Nasal bleeding can sometimes be life threatening. Therefore, the physician's first concern is to control the bleeding as quickly as possible. It is important that the physician be able to quickly and accurately insert the nasal packing into position.

   The problem is complicated by the fact that nasal bleeding can occur at any of a variety of locations within the nasal cavity. Anterior nasal bleeding can occur from the septum or turbinates lining the outer wall of the nasal cavity. Posterior nasal bleeding occurs within the nasopharynx. The problem is further complicated by the limited
visibility afforded the physician within the nasal cavity, particularly if bleeding is profuse. Insertion of nasal packing is often done by "feel". This makes it difficult for the physician to determine whether the nasal packing has been properly positioned, except by waiting to see whether bleeding continues. Such trial and error techniques can waste time and blood, causing unnecessary pain and discomfort for the patient, particularly if the nasal packing must be repositioned or replaced with a different type of device.

A wide variety of inflatable nasal packing devices have been invented in the past to control nasal bleeding, including the following:

<table>
<thead>
<tr>
<th>Inventor</th>
<th>Patent No.</th>
<th>Issue Date</th>
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<tbody>
<tr>
<td>Goldsmith et al.</td>
<td>5,139,510</td>
<td>Aug. 18, 1992</td>
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<tr>
<td>Kozlov et al.</td>
<td>5,024,658</td>
<td>June 18, 1991</td>
</tr>
<tr>
<td>Brennan</td>
<td>4,883,465</td>
<td>Nov. 28, 1989</td>
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<tr>
<td>Scheer</td>
<td>3,903,893</td>
<td>Sept. 9, 1975</td>
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<tr>
<td>Gottschalk</td>
<td>3,850,176</td>
<td>Nov. 26, 1974</td>
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<tr>
<td>Pidgeon</td>
<td>3,766,924</td>
<td>Oct. 23, 1973</td>
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<tr>
<td>Gottschalk</td>
<td>3,570,494</td>
<td>Mar. 16, 1971</td>
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<tr>
<td>Schlondorff</td>
<td>German OLS 2332554</td>
<td>Jan. 16, 1975</td>
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<tr>
<td>Ingelstedt et al.</td>
<td>Swedish Pat. 220978</td>
<td>June 4, 1968</td>
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The two Gottschalk patents (U.S. Patent Nos. 3,850,176 and 3,570,494) show a nasal packing device with two inflatable members or sleeves 12 and 16. One inflatable member is positioned in the nasal cavity and the other is located in the nasopharynx. Both inflatable members are illustrated as being balloons. Some nose bleeds occur from the turbinates lining the outer wall of the nose. The turbinates have highly convoluted surfaces that cannot be closely matched by a balloon due to the surface tension required to stretch the balloon during inflation. This substantially reduces the
effectiveness of a balloon in controlling bleeding from the turbinates. Gottschalk states that the balloon 96 is intended to stop nose bleeds by compressing the main artery to the interior of the nose (i.e., the sphenopalatine artery) as it enters the nasal cavity before it forms any branches (column 8, lines 56-67). This is diametrically opposed to the present invention which is intended to conform to irregularities within the nasal cavity and exert a uniform pressure throughout.

Goldsmith et al. disclose a nasal packing device having a splint 12 made of soft, flexible silicone and an attached inflatable membrane 60 for controlling anterior nose bleeds. The membrane 60 is inflated by means of a tube 30 bonded to the surface of the splint 12. However, this patent does not disclose a second balloon or a splint having a posterior portion that extends into the nasopharynx. In addition, the inflatable membrane extends only from one surface of the splint 12. The inflated membrane causes the splint to exert pressure against the patient's septum. The splint has a generally planar surface that may be effective in controlling bleeding from the septum, if the septum is substantially planar. Unfortunately, this assumption is not always true. Many patients have curved septums or septums with bone spurs, fractures, or other irregularities. Goldsmith et al. also depict the inflatable member 60 as a balloon-like structure.

The remaining references disclose other examples of nasal packing devices with multiple balloons or cuffs.

3. **Solution to the Problem.** None of the prior art references uncovered in the search show an inflatable nasal packing device having the present structure. The device includes a flexible keel that can be removably inserted through the nasal cavity and extends into
the nasopharynx. Two inflatable, oversized bags surround the anterior and posterior portions of the keel, respectively, so that the first bag fills the nasal cavity and the second bag fills the nasopharynx when inflated. This enables the present device to be used to control both anterior and posterior nasal bleeding. The inflatable bags are relatively large so that they can expand to conform to the turbinates and other irregularities in the nasal cavity and nasopharynx without stretching or distention. This allows the bags to exert a uniform pressure that is more effective in controlling bleeding. In addition, the inflatable bags completely surround the keel so that the keel is not forced against the septum.
SUMMARY OF THE INVENTION

This invention provides an inflatable nasal packing device having a flexible keel that can be removably inserted through the nasal cavity and into the nasopharynx. A first inflatable bag is attached to the anterior portion of the keel that remains within the nasal cavity, and a second inflatable bag is attached to the posterior portion of the keel extending into the nasopharynx. The bags completely surround the keel and are much larger than the relevant portions of the nasal cavity and nasopharynx. This helps to ensure that the bags conform to irregularities in and apply uniform pressure to the interior surfaces of the nasal cavity, including the nasal septum. The device is initially inserted into the nasal cavity with the bags in a deflated condition, and either or both of the bags are then inflated with air or fluid. When inflated, the first bag conforms to and blocks the nasal cavity without substantial distention. Similarly, the second bag conforms to and blocks the nasopharynx without substantial distention. Inflation and deflation of the bags is controlled by two catheters extending along the keel.

A primary object of the present invention is to provide an inflatable nasal packing device that is effective in treating both posterior nose bleeds and anterior nose bleeds.

Another object of the present invention is to provide an inflatable nasal packing device that conforms to irregularities within the nasal cavity and exerts a uniform pressure against the interior surfaces of the nasal cavity.
Yet another object of the present invention is to provide an inflatable nasal packing device that helps ensure uniform pressure is applied to the nasal septum when treating an anterior nose bleed.

These and other advantages, features, and objects of the present invention will be more readily understood in view of the following detailed description and the drawings.
BRIEF DESCRIPTION OF THE DRAWINGS

The present invention can be more readily understood in conjunction with the accompanying drawings, in which:

FIG. 1 is a side view of the nasal packing device 10.
FIG. 2 is a corresponding cross-sectional view of the keel 12 and one of the inflatable bags 30.
FIG. 3 is a cross-sectional view of the nasal cavity 50 and nasopharynx 60 of a patient prior to insertion of the device.
FIG. 4 is a cross-sectional view corresponding to FIG. 3 following initial insertion of the device 10.
FIG. 5 is a cross-sectional view corresponding to FIGS. 3 and 4 following inflation of the bags 30 and 40.
FIG. 6 is an anterior cross-sectional view of the inflated device within the nasal cavity, corresponding to FIG. 5.
DETAILED DESCRIPTION OF THE INVENTION

Turning to FIG. 1, the device 10 generally consists of two tandem inflatable bags 30, 40 surrounding a central keel 12. A corresponding cross-sectional view is illustrated in FIG. 2. The keel 12 serves a framework for the device 10 and acts as a guide for insertion to help ensure correct positioning of the device within the nasal cavity prior to inflating the bags 30 and 40. It is preferably made of a pliable, flexible material, such as silastic, latex, or another non-toxic material compatible with the nasal lining tissue. The keel 12 may have a hollow longitudinal section as shown in FIGS. 1 and 2.

FIG. 3 shows a cross-sectional view of the nasal cavity 50 prior to insertion of the device 10. The device 10 is designed to be easily inserted through the patient's nostril with the bags 30, 40 deflated, as shown in FIG. 4. The length of the keel 12 is selected so that the posterior portion of the keel extends into the nasopharynx 60 when the anterior portion of the keel is positioned within the nasal cavity 50. Optionally, the upper edge of the anterior portion of the keel can be contoured to match the contour of the upper surface of the nasal cavity 50 to further assist in properly positioning the device 10 within the nasal cavity.

A first inflatable bag 30 is attached to the anterior portion of the keel 12, as depicted in FIG. 1. Similarly, a second inflatable bag 40 is attached to the posterior portion of the keel 12. The bags are made of a thin, flexible plastic film, such as polyethylene. The first bag 30 is oversize in relationship to the volume of the nasal cavity 50, while the second bag 40 is oversize in relationship to the volume of the nasopharynx 60. The device 10 would normally be inserted into the
nasal cavity 50 with the bags in a deflated state to minimize patient discomfort as shown in FIG. 4. An ointment (e.g., antibiotic ointment) can be used to coat the exterior surfaces of the bags for lubrication and to help prevent infection.

Following insertion of the device 10, either of the bags 30, 40 can be independently inflated by supplying pressurized air or fluid from an external source through corresponding tubes 36, 46 which lead to two catheters 32, 42 extending along the keel 12. This is shown most clearly in FIGS. 5 and 6. The air or fluid flows through a series of fenestrations 34 in the first catheter 32 to inflate the first bag 30. Similarly, the second bag 40 can be independently inflated through fenestrations 44 in the second catheter 42. Control valves 38, 48 prevent escape of the air or fluid after the bags 30, 40 have been inflated.

When the first bag 30 is inflated, it substantially blocks the nasal cavity 50 without a significant degree of stretching or distention due to the relatively large dimensions of the bag 30. This allows the bag 30 to conform to irregularities in the size and shape of the nasal cavity 50. The side walls of the nasal cavity are lined by a series of ridges 55 of bone covered with soft tissue, commonly known as the turbinates, shown in FIGS. 3 and 6. The turbinates 55 create very irregular, convoluted surfaces to which a balloon cannot conform. In contrast, the flexible, oversized bag 30 in the present invention is much better at adapting to such irregular surfaces. The bag can also fold onto itself and create invaginations in regions where the nasal cavity 50 is constricted. This makes the present invention especially well suited for treating patients who have septal deviation, suffered trauma, or undergone surgery involving the nasal cavity. When
inflated, the bag 30 applies evenly distributed pressure on the interior surfaces of the nasal cavity 50 to terminate nasal hemorrhage.

The second bag 40 is designed in a similar manner with dimensions sufficiently large to substantially block the nasopharynx 60 without stretching or distending the bag, as shown in FIGS. 5 and 6. Here again, the second bag 40 is sufficiently oversized and flexible to conform to irregularities in the interior surfaces of the nasopharynx 60, and results in a relatively uniform application of pressure on the interior surfaces of the nasopharynx 60 to terminate nasal hemorrhage.

Each bag 30 and 40 can be independently deflated following treatment by opening their respective control valves 38 and 48. The device 10 can be removed from the nasal cavity through the patient's nostril by pulling on the keel 12 or the tubes 36, 46.

In the preferred embodiment of the present invention, the first bag 30 completely surrounds the anterior portion of the keel 12 to separate the keel 12 from the septum 70 when the bag 30 is inflated. As shown in FIG. 6, this allows the bag 30 to conform to the contours of the septum 70 and results in a more uniform application of pressure. The second bag 40 can also be designed to completely surround the posterior portion of the keel 12 to provide a more uniform pressure distribution within the nasopharynx 60.

A cord or rib 35, 45 extends along the periphery of the bags 30, 40 to simplify insertion of the device and to help ensure complete deflation of bags. Otherwise, the bags tend to collapse too quickly during the deflation process and seal the fenestrations 34, 44 while some of the inflation fluid remains in the bags. The cord causes the collapsing bag to form a tent-like structure that allows substantially all of the inflation fluid to drain out through the fenestrations 34, 44.
The above disclosure sets forth a number of embodiments of the present invention. Other arrangements or embodiments, not precisely set forth, could be practiced under the teachings of the present invention and as set forth in the following claims.
I CLAIM:

1. An inflatable nasal packing device for removable insertion into the nasal cavity and nasopharynx of a patient; said nasal packing device comprising:
   a keel having:
   (a) an anterior portion for removable insertion into said nasal cavity; and
   (b) a posterior portion extending from said anterior portion of said keel into said nasopharynx when said anterior portion is positioned within said nasal cavity;
   a first inflatable bag attached to said anterior portion of said keel having a deflated state during insertion of said keel and an inflated state in which said first bag substantially conforms to and blocks said anterior portion of said nasal cavity without substantial distention of said first bag; and
   a second inflatable bag attached to said posterior portion of said keel having a deflated state during insertion of said keel and an inflated state in which said second bag substantially conforms to and blocks said nasopharynx without substantial distention of said second bag.

2. The inflatable nasal packing device of claim 1, wherein said keel comprises a flexible member for insertion through the patient’s nostril, said flexible member having sufficient length to extend from said nostril through said nasal cavity and into said nasopharynx.
3. The inflatable nasal packing device of claim 1 wherein said keel is comprised of silastic.

4. The inflatable nasal packing device of claim 1 wherein said keel is comprised of latex.

5. The inflatable nasal packing device of claim 1, further comprising means for selectively inflating and deflating said first and second bags.

6. The inflatable nasal packing device of claim 1 further comprising a first catheter extending along said keel for inflation of said first bag and a second catheter extending along said keel for inflation of said second bag.

7. The inflatable nasal packing device of claim 1 wherein the patient's septum forms the medial border of said anterior portion of said nasal cavity, and wherein said first bag surrounds said anterior portion of said keel to separate said keel from said septum when said first bag is inflated.

8. The inflatable nasal packing device of claim 1 wherein said second bag surrounds said posterior portion of said keel.

9. The inflatable nasal packing device of claim 1 further comprising a coating of ointment on said first and second bags.
10. The inflatable nasal packing device of claim 1 further comprising a cord extending along the periphery of said first and second bags.

11. An inflatable nasal packing device for removable insertion into the nasal cavity and nasopharynx of a patient; wherein said nasal packing device comprises:

   a keel having:

   (a) an anterior portion for removable insertion into said nasal cavity; and

   (b) a posterior portion extending from said anterior portion of said keel into said nasopharynx when said anterior portion is positioned within said anterior portion of said nasal cavity;

   a first inflatable bag attached to and surrounding said anterior portion of said keel with inflated dimensions substantially larger than said nasal cavity; said first bag having a deflated state during insertion of said keel into said nasal cavity and an inflated state in which said first bag conforms to and blocks said nasal cavity without substantial distention of said first bag while separating said keel from said patient's septum;

   a second inflatable bag attached to and surrounding said posterior portion of said keel with inflated dimensions substantially larger than said nasopharynx; said second bag having a deflated state during insertion of said keel and an inflated state in which said second bag conforms to and blocks said nasopharynx without substantial distention of said second bag; and

   means for selectively inflating and deflating said first and second inflatable bags.
12. The inflatable nasal packing device of claim 11 wherein said keel comprises a flexible member for insertion through the patient's nostril, said flexible member having sufficient length to extend from said nostril through said nasal cavity and into said nasopharynx.

13. The inflatable nasal packing device of claim 11 wherein said keel is comprised of silastic.

14. The inflatable nasal packing device of claim 11 wherein said keel is comprised of latex.

15. The inflatable nasal packing device of claim 11 wherein said means for inflating said first and second bags comprise a first catheter extending along said keel for inflation of said first bag and a second catheter extending along said keel for inflation of said second bag.

16. The inflatable nasal packing device of claim 11 further comprising a coating of ointment on said first and second bags.

17. The inflatable nasal packing device of claim 11 further comprising a cord extending around the periphery of said first and second bags.

18. An inflatable nasal packing device for removable insertion into the nasopharynx and nasal cavity adjacent to the septum of a patient; wherein said device comprises:

(a) an anterior portion for removable insertion into said
nasal cavity; and

(b) a posterior portion extending from said anterior portion
of said keel into said nasopharynx when said anterior portion is
positioned within said nasal cavity;

10 a first inflatable bag attached to and surrounding said anterior
portion of said keel, said first inflatable bag having a deflated state
during insertion of said keel and an inflated state in which said first
inflatable bag substantially blocks said nasal cavity and separates
said keel from said patient's septum without substantially stretching
said first bag;

15 a first catheter extending along said keel for inflation of said
first inflatable bag;

a second inflatable bag attached to and surrounding said
posterior portion of said keel, having a deflated state during insertion
of said keel and an inflated state in which said second inflatable bag
substantially blocks said nasopharynx and separates said keel from
said nasopharynx without substantially stretching said second bag;

20 a second catheter extending along said keel for inflation of said
second inflatable bag; and

25 means for selectively inflating and deflating said first and
second inflatable bags through said first and second catheters.

19. The inflatable nasal packing device of claim 18 further
comprising a coating of ointment on said first and second bags.

20. The inflatable nasal packing device of claim 18 further
comprising a cord extending around the periphery of said first and
second bags.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
   IPC(6) :A61M 29/00
   US CL -606/196
   According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
   Minimum documentation searched (classification system followed by classification symbols)
   U.S. : 604/94, 96-104; 606/190-200; 604/94,96-104
   Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

   Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>X</td>
<td>US, A, 3,903,893 (SCHER) 09 September 1975, see Fig. 3.</td>
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<td>Y</td>
<td>see fig. 3</td>
<td>9, 16, 19</td>
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<td>Y, P</td>
<td>US, A, 5,496,345 (KETURAKIS ET AL.) 05 March 1996,</td>
<td>10, 17, 20</td>
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<td>see entire document.</td>
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<td>X</td>
<td>DT, A, 2,332,554 (G SCHLONDORF) 16 January 1975,</td>
<td>1, 2, 5-8, 11,</td>
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☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
  "A" document defining the general state of the art which is not considered
  to be part of particular relevance
  "E" earlier document published on or after the international filing date
  "L" document which may throw doubts on priority claim(s) or which is
  cited to establish the publication date of another citation or other
  special reason (as specified)
  "O" document referring to an oral disclosure, use, exhibition or other
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   date and not in conflict with the application but cited to understand the
   principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be
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   when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be
   considered to involve an inventive step when the document is
   combined with one or more other such documents, such combination
   being obvious to a person skilled in the art

"A" document member of the same patent family

Date of the actual completion of the international search: 05 JULY 1996
Date of mailing of the international search report: 02 AUG 1996

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
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Washington, D.C. 20231
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Form PCT/ISA/210 (second sheet)(July 1992)*